



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-1026; FRL-9380-6]

Banda de *Lupinus albus* doce (BLAD); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of banda de *Lupinus albus* doce (BLAD), a naturally occurring polypeptide from the catabolism of a seed storage protein (β -conglutin) of sweet lupines (*Lupinus albus*), in or on all food commodities when applied as a fungicide and used in accordance with label directions and good agricultural practices. On behalf of Consumo Em Verde S.A., Bert Volger of Ceres International LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of BLAD under the FFDCA.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-1026, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Menyon Adams, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8496; email address: adams.menyon@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at

<http://ecfr.gpoaccess.gov/cgi/t/text/text->

[idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to

<http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-1026 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA

without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-1026, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL-9335-9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F7917) by Bert Volger of Ceres International LLC, 1087 Heartsease Drive, West Chester, PA 19382, on behalf of Consumo Em Verde S.A, Biotechnologia De Plantas, Parque Tecnologico de Cantanhede, Nucleo 04, Lote 2, 3060-197 Cantanhede, Portugal. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of BLAD. This notice referenced a summary of the petition prepared by the petitioner, Bert Volger of Ceres International LLC (on behalf of

Consumo Em Verde S.A.), which is available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance exemption and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second,

EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

BLAD, used as a fungicide, is a naturally occurring 20 kilo Dalton (kDa) polypeptide of β -conglutin formed during days 4 to 12 of the germination process of the flowering plant, sweet lupines (*Lupinus albus*). It is also characterized as a fragment of the amino acid sequence of β -conglutin and the main storage protein in sweet lupines with a long history of safe use in human and livestock consumption without any adverse effects. (Ref. 1).

Lupinus albus, commonly known as white or sweet lupine or lupin, is a member of the genus *Lupinus* in the family of Fabaceae. *Lupinus albus* contains the full range of essential amino acids and for hundreds of years has been widely cultivated worldwide; for example, in the Mediterranean Basin and also Egypt, Sudan, Ethiopia, Syria, Central and Western Europe, the United States and South America, Tropical and Southern Africa, Russia and the Ukraine. (Ref. 1).

BLAD is directly extracted from the flowering plant, sweet lupines. It has a dark brown color with a sweet odor and is 60% biodegradable within 14 days after application. (Ref. 1). Data submitted and reviewed by the Agency demonstrate that BLAD has a

nontoxic mode of action in that it binds to chitin, a major component of the fungal cell wall, thereby inhibiting any fungal growth. (Ref. 1). More specifically, BLAD degrades chitin by catalyzing and successfully removing the N-acetyl-D-glucosamine terminal monomers, resulting in the destruction of the fungal cells. (Ref. 1).

All of the data requirements to support a tolerance exemption were fulfilled by the applicant. EPA concluded that the data are acceptable and no additional data are required. No acute, subchronic, or chronic toxicity endpoints were identified in guideline studies or in data obtained from open technical literature. Moreover, BLAD is not a mutagen, and is not a developmental toxicant. There are no known effects on endocrine systems via oral, dermal, or inhalation exposure. (Ref. 1).

Summaries of the toxicological data submitted by the petitioner in support of this tolerance exemption follows:

Acute toxicity. Acute toxicity studies confirm BLAD's low toxicity profile for all routes of exposure. For more information about the Toxicity Categories mentioned in the summaries directly below refer to 40 CFR 156.62.

1. The acute oral median lethal dose (LD_{50}) in rats was greater than 5,000 milligrams per kilogram of bodyweight (mg/kg/bwt). There were no observed toxicological effects on the test subjects in the acute oral study submitted by the petitioner. BLAD is classified as Toxicity Category IV for acute oral toxicity. (Harmonized Guideline 870.1100; Master Record Identification (MRID) No. 48587904). (Ref. 1).

2. The acute dermal LD₅₀ in rats was greater than 2,000 mg/kg/bwt. BLAD is classified as Toxicity Category III for acute dermal toxicity. (Harmonized Guideline 870.1200; MRID No. 48587905). (Ref. 1).

3. The acute inhalation median lethal concentration (LC₅₀) was greater than 5.34 milligrams per liter (mg/L) in rats and showed no significant inhalation toxicity. BLAD is classified as Toxicity Category IV for acute inhalation toxicity. (Harmonized Guideline 870.1300; MRID No. 48587906). (Ref. 1).

4. A primary eye irritation study on rabbits indicates that BLAD is mildly irritating to the eye. BLAD is classified as Toxicity Category III for primary eye irritation. (Harmonized Guideline 870.2400; MRID No. 48587907). (Ref. 1).

5. A skin irritation study on rabbits indicates that BLAD is mild to slightly irritating to the skin. BLAD is classified as Toxicity Category IV for primary dermal irritation. (Harmonized Guideline 870.2500; MRID No. 48587908). (Ref. 1).

6. Data indicate that BLAD is not a contact dermal sensitizer. (Harmonized Guideline 870.2600; MRID No. 48587909). (Ref. 1).

Scientific rationale and public literature were provided to fulfill the following data requirements: 90-Day Oral (Harmonized Guideline 870.3100), 90-Day Dermal (Harmonized Guideline 870.3250), 90-Day Inhalation (Harmonized Guideline 870.3465), Prenatal Development (Harmonized Guideline 870.3700), Bacterial Reverse Mutation Test (Harmonized Guideline 870.5100), *In vitro* Mammalian Chromosome Aberration (Harmonized Guideline 870.5375). (Ref. 1).

According to the acceptable scientific information submitted in lieu of a study in satisfying the data requirements provided to EPA (MRID No's. 485879109 – 48587914),

BLAD has the following properties and characteristics:

- i. BLAD is used in human and animal nutrition as a food and feed item; and
- ii. BLAD has a nontoxic mode of action against fungal pests and 60% is biodegradable within 14 days in the environment, thereby minimizing any potential for toxic risk, such that there is no concern for potential exposure. (Ref. 1).

Additionally, EPA reviewed studies pertaining to the chronic exposure of lupine products. One study of the potential reproductive and developmental toxicity of lupin protein was identified in the literature (Ref. 2). Dietary administration of 20% lupin protein isolated from *Lupinus albus* administered to 3 generations of rats for 270 days each (providing 7 to 35.4 grams lupin protein/kg/bwt/day over the study duration) was reported to result in significantly decreased relative liver weights in both sexes in the second and third generation rats; however, these changes were not accompanied by any histological changes. No other effects on organ weights occurred, and the lupin protein was reported to have no effect on either fertility or reproductive parameters in any of the generations (Ref. 2). Studies of the mutagenic/genotoxic potential of lupin or its fractions were not identified in the literature, nor were traditional carcinogenicity studies; however, chronic life-time studies (i.e., 700 and 800 days) in rats did not reveal any evidence of carcinogenicity in lupin-treated animals, and no signs of toxicity or decreases in body weight occurred (Refs. 3 and 4).

IV. Aggregate Exposure

In examining aggregate exposure, FFDCa section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface

water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Dietary risks to humans are considered negligible, based on the lack of dietary toxicological endpoints for BLAD and its nontoxic mode of action as a fungicide. No acute, subchronic, mutagenic, immunotoxic, developmental, or chronic dietary hazards were identified in the studies and information submitted to support this exemption from the requirement of a tolerance. Based on BLAD's lack of dietary toxicity hazards for mammals, no dietary exposure concerns are expected.

1. *Food.* While the proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities, minimal to no risk is expected for the general population, including infants and children, or animals because BLAD has low toxicity, has a history of safe consumption and degrades rapidly.

2. *Drinking water exposure.* The potential for transfer of BLAD to surface or ground water associated with intended use applications is considered minimal to non-existent due to the low application rate and rapid biodegradation of BLAD. In the unlikely event that residues of BLAD in water exceed currently existing background levels, the toxicity data demonstrate a lack of toxicity by the oral route of exposure.

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected because BLAD will not be applied in residential settings. BLAD is applied directly to food commodities and degrades rapidly after application.

1. *Dermal exposure.* No non-occupational dermal exposures are expected to result from the agricultural uses of BLAD. Any dermal exposure is expected to be occupational in nature.

2. *Inhalation exposure.* No non-occupational inhalation exposures are expected to result from the agricultural uses of BLAD. Any inhalation exposure is expected to be occupational in nature.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA has not found BLAD to share a common mechanism of toxicity with any other substances, and BLAD does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that BLAD does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine chemicals that have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the

cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCa section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data are available to support the choice of a different safety factor.

The acute, subchronic, and developmental toxicity data discussed in Unit III. indicate that BLAD has negligible toxicity. In addition, BLAD is used in human and animal nutrition as a food and feed item, has a nontoxic mode of action against fungal pests, and rapidly degrades in the environment. EPA therefore concludes that there are no threshold effects of concern to infants, children, or adults when BLAD is applied as a fungicide and used in accordance with label directions and good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

Moreover, based on the same data and EPA analysis as presented directly above, EPA is able to conclude that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of BLAD when it is applied as fungicide and used in accordance with label directions and good agricultural practices. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this

conclusion because, considered collectively, the data and information available on BLAD do not demonstrate toxic potential to mammals, including infants and children.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated above and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitations.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for BLAD.

VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of BLAD. Therefore, an exemption from the requirement of a tolerance is established for

residues of BLAD, a naturally occurring polypeptide from the catabolism of a seed storage protein (β -conglutin) of sweet lupines (*Lupinus albus*), in or on food commodities when applied as a fungicide and used in accordance with label directions and good agricultural practices.

IX. References

1. U.S. EPA. 2012. Memorandum from Miachel Rexrode, Ph.D., Senior Biologist to Menyon Adams, Biologist. Request for a new product registration for β -Conglutin Section 3 with tolerance. Science Review of Product Chemistry, non-Target Organism and Toxicity Data in support of new product registration. U.S. Environmental Protection Agency Office of Pesticide Programs. May 24, 2012.
2. Ballester, D.R.; Brunser, O.; Saitua, M.T.; EgaAa, J.I.; Yaieez, E.O.; Owen, D.F. 1984. Safety evaluation of sweet lupine (*Lupinus albus* cv. Multolupa). II. Nine-month feeding and multigeneration study in rats. *Food and Chemical Toxicology* 22(1):45-48.
3. Grant, G.; Dorward, P.M.; Pusztai, A. 1993. Pancreatic enlargement is evident in rats fed diets containing raw soybeans (*Glycine rnax*) or cowpeas (*Vigna unguiculata*) for 800 days but not in those fed diets based on kidney beans (*Phaseolus vulgaris*) or lupinseed (*Lupinus angustifolius*). *Journal of Nutrition* 123(12):2207-2215.
4. Grant, G.; Dorward, P.M.; Buchan, W.C.; Armour, J.C.; Pustzai, A. 1995. Consumption of diets containing raw soya beans (*Glycine rnax*), kidney beans (*Phaseolus vulgaris*), cowpeas (*Vigna unguiculata*) or lupin seeds (*Lupinus angustifolius*) by rats for up to 700 days: Effects on body composition and organ weights. *British Journal of Nutrition* 73(1):17-29.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 29, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.1319 to subpart D to read as follows:

§180.1319 Banda de *Lupinus albus* doce (BLAD); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of Banda de *Lupinus albus* doce (BLAD), a naturally occurring polypeptide from the catabolism of a seed storage protein (β -conglutin) of sweet lupines (*Lupinus albus*), in or on all food commodities when applied as a fungicide and used in accordance with label directions and good agricultural practices.

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